K003029

DEC - 4 2000

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92."

"The assigned 510(k) number is: _____."

1. Submitter Information: **September 2000**

B. Braun Medical Inc.
1601 Wallace Drive Ste. 150
Carrollton, TX. 75006
(972) 245-2243 ext. 206

Contact Person: Mr. Gary A. Gulyas
Quality Manager
Phone: 972.245.2243 ext. 206
FAX: 972.245.0952

2: Name of Device: **Infusion Pump**

Trade Name: **Infusomat® P**

Classification Name: **Class II, 80FRN**
21 CFR 880.5725

Additionally, since the subject infusion pump is labeled and intended for use for enteral infusions, the product code, **80 LZH** for Enteral Infusion Pumps also applies.

3: Predicate Device:

The predicate device that B. Braun Medical Inc. is claiming substantial equivalence[1] to is the Sigma 8000, marketed under cleared 510(k) 950766 by Sigma International. The Sigma 8000 is an external linear peristaltic volumetric infusion pump. There are no new issues of safety or effectiveness raised by the Infusomat® P.

[1] The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

4: Description of the Subject Device:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical Inc. intends to introduce into interstate commerce the Infusomat® P Infusion Pump. The Infusomat® P is an external volumetric infusion pump that is suitable for dispensing liquids in nutritional and infusion therapy.

The infusion pump contains the following hardware assemblies: linear peristaltic pumping mechanism assembly, power supply assembly, pole clamp assembly, display assembly, and electronics assembly. The power supply cord can be mounted and removed from a receptacle in the rear of the pump. The battery power supply consists of rechargeable 12 volt battery pack . The display subassembly contains an LCD display and a keypad used to input data into the pump as well as to present pump status and information to the user.

The electronics subassembly contains all of the electronics in the pump, including the microprocessors that run the software. The electronics subassembly also contains communications electronics that will allow the pump to transmit and receive messages to and from external devices, including personal computers and hospital monitoring systems.

The software provides communication capabilities from the pump to external communication devices. This includes transmission of the following information: Operation / Alarm Log, pump status and pump configuration / calibration data. The software also provides communication abilities from external devices to the pump. This feature is only accessible by a trained Biomedical Technician. Programming of the pump is to be performed by trained biomedical professionals.

5: Intended Use of the Subject Device:

The system created by using the Infusomat® P with disposable tubing validated for use with the pump is intended to provide accurate and continuous flow of parenteral and enteral fluids to the patient. The pump is software controlled and operates using a linear peristaltic mechanism.

The Infusomat® P is intended for but not limited to use in the hospital, home care and/or nursing home (extended care) settings. The Operation Manual is intended to reinforce the teaching given to the user by a trained healthcare professional or an authorized B. Braun Medical Inc. representative. A trained Biomedical Technician must perform a full set-up of the pump before use in a clinical setting.

6: Technological Characteristics of the Subject Device

The subject device, Infusomat® P is substantially equivalent to the predicate device, the Sigma 8000. The subject and predicate devices are similar in design, material composition, components, manufacturing process, intended use and labeling. The substantial equivalence claim between the subject and predicate device is supported by the information and data provided in this 510(k) submission.
This includes the following information:

- Description of the subject and predicate devices.
- Intended use of the subject and predicate devices.
- Material composition of the subject and predicate devices.
- Labels and labeling for the subject and predicate devices.
- Comparison tables of attributes and specifications of the subject and predicate devices.
- Subject device customer functional specification.
- Subject device system and software hazard analysis.
- Subject device system and software requirements.
- Subject device system and software test plans.
- Subject device system and software test matrix.

7: Signature of Applicant

B. Braun Medical Inc.
Gary A. Gulyas
Quality Manager

Signature

September 26, 2000
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. Gary A. Gultas
Quality Manager
B. Braun Medical, Incorporated
1601 Wallace Drive, Suite 150
Carrollton, Texas 75006

Re: K003029
Trade Name: Infusomat® P Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: September 25, 2000
Received: September 28,2000

Dear Mr. Gultas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Gerald W Shipps for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known)

Device Name: Infusomat® P Infusion Pump

Indications For Use:

The Infusomat® P is an external volumetric infusion pump that provides infusions of parenteral and enteral fluids. The system created using disposable tubing validated for use with the Infusomat® P is intended to provide accurate and continuous flow of parenteral fluids and enteral feedings to the patient. Parenteral fluids may include all standard fluids and/or medications indicated for infusion as well as blood and blood products. The pump is software controlled and operates using a linear peristaltic mechanism.

The Infusomat® P is intended for but not limited to use in the hospital, home care and/or nursing home (extended care) settings. The Infusomat® P is intended for use by trained healthcare providers in accordance with the instructions provided in the Operation Manual. All data entry and validation of parameters is performed by the trained healthcare provider per a physician's order.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cucento

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003029